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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,104	06/18/2002	Yves Prat	219664US2XPCT	7891

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EXAMINER	
GABOR, OTILIA	

ART UNIT	PAPER NUMBER
2878	

DATE MAILED: 06/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/069,104	PRAT ET AL.	
	Examiner	Art Unit	
	Otilia Gabor	2878	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 February 2002 and 18 June 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 June 2002* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *02/26/2002*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to because they contain references in foreign language; the inclusion of the English translation within the drawing sheet does not overcome the objection. Corrected drawing sheets are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 24 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 24 provides for the use of the device, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 24 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 13, 14, 18, 22, 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lim et al. (U. S. Patent 5,491,342).

Lim et al. discloses an apparatus and method for measuring the interaction of radiation with a material, the device comprising:

- a primary radiation source (radionuclide source inserted into the body of the patient) for emitting radiation that had interacted with the material (patient body)
- a photomultiplier (PMT) 12 for measuring the radiation emitted from the material
- a scintillator disposed across the entrance of the PMT
- a calibration source (see Col.3, lines 30-66) for illuminating the PMT with a radiation having a known energy whereby the PMT measures the radiation coming from the calibration source.

In operation, the calibration source is positioned so as to provide a uniform source of photons over the field of view of the PMT. The radiation intensity coming from the calibration source is measured and the value is stored in the memory 22, 24, 26. After the calibration value is stored, the PMT is exposed to the radiation coming from the primary radiation source, which interacted with the material sample (patient body)

and the intensity of the measured radiation is determined. The correction processor 20 uses these two values, the measured radiation intensity and the calibration radiation intensity, to determine the actual correct value of the radiation after the interaction with the body, i.e., the measuring device is calibrated. Lim et al. fails to specify that the PMT is equipped with a main window and a photocathode, however these are inherently present since it is well known that the main components of a PMT are an entrance window and a photocathode (see Wojcik et al. 6,740,859).

Regarding claim 13, Lim et al. fails to specifically disclose that there is a means for turning off the radiation source or for blocking the radiation to be measured and a means for activating the calibration source exclusively during periods when the radiation is turned off or blocked. However, since Lim et al. discloses that the primary radiation source measurement is done after the calibration measurement is finished and the calibration values stored (i.e., the calibration source is activated exclusively when the other measurement radiation is not present), it is inherently understood that the calibration and the measurement are not done simultaneously but one after the other. As such, means to turn on and off or to block the measurement radiation and means to activate the calibration source when the measurement source is turned off or blocked must be inherently present, for otherwise the two measurements cannot be exclusive from each other.

Regarding claim 14, Lim et al. fails to disclose that a ratio of the two radiation measurements is done, however since he discloses that the processor 20 uses the calibration measurement and the radiation measurement from the body to adjust the

calibration of the device (i.e., to calculate the final value of the intensity of radiation) according to the relationship between the two measurements using several different conventional methods, it would have been obvious to one of ordinary skill in the art to use the ratio between the two measurement values since a ratio between the measurements represents a conventional relationship between the two (underline added for emphasis). The conditions during the two measurements are not changed.

Regarding claim 18, Lim et al. discloses that the material (body) is disposed between the primary source (radioisotope) and the measuring device.

8. Claims 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lim et al. and further in view of Kobayashi (EP 0387799 A2).

Lim et al. fails to specify that the calibration source is an LED that is disposed across the main entrance window of the PMT where the LED emits directly toward the photocathode without passing through the scintillator. However, since he fails to specifically limit the type of calibration sources and the positioning of the source in the system, one of ordinary skill in the art would be motivated to use any conventionally available sources and to position it at the most convenient site to do the measurement. As such, one would be motivated to use an LED as the calibration source as taught by Kobayashi since it is a conventionally used light source that provides a standard light beam and it's ample in quantity, and would also be motivated to position the LED on the front face window of the PMT as taught by Kobayashi since positioning it directly on the PMT will assure that the light from the LED reaches the photocathode of the PMT without any disturbance.

9. Claims 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lim et al. and further in view of Karellas (U. S. Patent 5,864,146) and Gillard et al. (U. S. Patent 4,366,395).

Regarding claims 19-21 Lim et al. fails to disclose an embodiment where instead of using the radioisotope as the primary source an X-ray tube is utilized, however this switch would have been obvious to one of ordinary skill in the art at the time the invention was made since, as shown by Karellas, radiographic imaging (measuring interaction of radiation with a material) of a patient's body (material) can be done either by using radioisotopes as the primary radiation source or using an X-ray source separate from the body (see Col.1, lines 64-67, Figs.1, 8, 11), and since the calibration method of Lim et al is not dependent on the type of primary radiation source present. Though, Karellas does not specifically disclose the components of the X-ray tube 12 used, it is well known, as presented by Gillard et al., that a typical X-ray tube with a filament includes an anode, and a cathode whereby, when the X-ray tube need not be on all the time, it also comprises a means for applying a high alternating voltage between the anode and the cathode (see Col.1, lines 1-55). One of ordinary skill in the art would have been motivated to use the pulsed X-ray tube of Gillard et al. as the primary radiation source since that would eliminate the need to include other components to allow for turning on and off the primary source in order to take the calibration measurements. Thus, the system is more compact.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Otilia Gabor whose telephone number is 571-272-2435. The examiner can normally be reached on Monday-Friday between 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Porta can be reached on 571-272-2444. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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